Complete Summary

GUIDELINE TITLE

Diagnosis and management of asthma.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 May. 49 p. [37 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Asthma

- Acute asthma
- Chronic asthma

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Internal Medicine

Pediatrics
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To promote the accurate assessment of asthma severity through the use of objective measures of lung function
- To promote long-term control of persistent asthma through the use of corticosteroid drug therapy
- To promote the partnership of patients with asthma and/or their parents with health care professionals through education and use of written action plans

TARGET POPULATION

Patients over 5 years of age who present with asthma-like symptoms and/or have been diagnosed with asthma

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic Assessments (at Initial Diagnosis and Interval Evaluations)

1. Patient's medical history
2. Physical examination
3. Asthma triggers/allergens assessment
4. Pulmonary function tests: spirometry, including measurements of forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), ratio of forced expiratory volume in 1 second to forced vital capacity (FEV_1/FVC), or peak expiratory flow rate (PEFR)
5. Additional laboratory tests, such as oxygen saturation, arterial blood gases, chest x-ray, complete blood count with eosinophils, total immunoglobulin E, sputum exam, bronchial provocation tests, electrolytes, electrocardiogram, and evaluation for gastroesophageal reflux disease (GERD)
6. Assessment of asthma severity, based on frequency and severity of symptoms, frequency and severity of exacerbations, and spirometry measurements
7. Specialty consultation as indicated

Management of Acute Asthma

1. Review of history and physical exam

2. Treatment with beta$_2$-agonists (albuterol), epinephrine, ipratropium added to nebulized beta2-agonist (albuterol), levalbuterol, oral corticosteroids (e.g., prednisone), inhaled corticosteroids, inhaled beta$_2$-agonists, cromolyn/nedocromil, and leukotriene modifiers, antibiotics, with treatment based on response (emergency care or home treatment)
3. Assessment of response based on pulmonary function tests and symptoms
4. Patient education and follow-up

Step Care of Pharmacologic Treatment (Long Term Control of Asthma Symptoms with the Least Amount of Medication Necessary)

1. Systemic corticosteroids, such as methylprednisolone, prednisolone, prednisone
2. Cromolyn sodium (Intal) and nedocromil (Tilade)
3. Long-acting beta$_2$-agonists, such as salmeterol, formoterol fumarate, fluticasone propionate, sustained-release albuterol
4. Methylxanthines, such as theophylline (Theodur, Slo-bid, Slo-Phyllin, Uniphyl, and others) or aminophylline
5. Leukotriene modifiers, such as montelukast (Singulair), zafirlukast (Accolate), and zileuton (Zyflo)
6. Inhaled corticosteroids, such as beclomethasone dipropionate and hydrofluoroalkane (HFA) formulations (Beclovent, Vanceril), budesonide dry powder inhaler (DPI) (Pulmicort), flunisolide (metered dose inhaler and dry powder inhaler formulations) (Aerobid, Aerobid-M), fluticasone (Flovent), fluticasone propionate/salmeterol combinations, and triamcinolone acetonide (Azmacort)
7. Short-acting inhaled beta$_2$ -agonists in metered-dose and dry powder formulations, such as albuterol (Ventolin, Proventil), albuterol hydrofluoroalkane (Proventil HFA), bitolterol, pirbuterol (Maxair), levalbuterol (Xopenex)
8. Anticholinergics, such as ipratropium

Asthma Education -- Stepped Approach

1. Education in basic facts about asthma
2. Education in inhaler technique
3. Written action plan, including home peak flow rate monitoring
4. Environmental control measures
5. Emphasis on regular follow-up visits

MAJOR OUTCOMES CONSIDERED

- Asthma symptom control
- Sensitivity and specificity of diagnostic tests
- Asthma morbidity measures such as level of physical activity, lost work days, unscheduled office visits, and emergency room and hospital admissions
- Side effects or complications of asthma pharmacotherapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systemic review
- Decision analysis
- Cost-effectiveness study

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its

operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Respiratory Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for six months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Respiratory Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for diagnosis and management of asthma are presented in the form of an algorithm, Diagnosis and Management of Asthma, with 10 components, accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and key conclusions (I-IV) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Conduct interval evaluations of asthma including medical history and physical examination, assessment of asthma triggers and allergens, measurement of pulmonary function, and consideration of consultation and/or allergy testing. (Annotation #6)
2. Regularly assess asthma control. (Annotation #7)

3. Match medical intervention with asthma severity and adjust to correspond with change over time. (Annotation #8; see also Table 8A in original guideline document)
4. Achieve effective control of chronic persistent asthma through use of anti-inflammatory drug therapy. (See Table 8A in original guideline document)
5. Provide asthma education to adult patients and parents of pediatric patients. Education should include basic facts about asthma, inhaler technique, a written action plan including home peak flow rate monitoring or a symptom diary, environmental control measures, and emphasis on the need for regular follow-up visits. (Annotation #9)

Diagnosis and Management of Asthma Algorithm Annotations

3. Establish Diagnosis of Asthma

The diagnosis of asthma is based on the patient's medical history, physical examination, pulmonary function tests, and laboratory test results. Spirometry is recommended for the diagnosis of asthma.

A. Asthma triggers
    1. Viral respiratory infections
    2. Environmental allergens
    3. Exercise, temperature, humidity
    4. Occupational and recreational allergens or irritants
    5. Environmental irritants (perfume, tobacco smoke, wood burning stoves)
    6. Drugs (aspirin, nonsteroidal anti-inflammatory drugs [NSAIDs], beta blocker) and food (sulfites)

B. Other historical components
    1. Emergency room visits and hospitalization
    2. Medication use (especially oral steroids)
    3. Lung function, peak expiratory flow rate (PEFR) variability
    4. Associated symptoms, e.g., rhinitis, sinusitis, gastroesophageal reflux disease (GERD)

C. Laboratory evaluation
    1. Accurate spirometry is recommended in every patient $\geq$5 years of age at the time of diagnosis.
    2. Additional studies done, tailored to the specific patient.
        - Allergy testing (skin testing, in vitro specific immunoglobulin E [IgE] antibody testing)
        - Chest radiography, to exclude alternative diagnosis
        - Bronchial provocation testing if spirometry is normal or near normal
        - Sinus x-rays or computed tomography (CT) scan
        - Gastroesophageal reflux disease (GERD) evaluation
        - Complete blood count (CBC) with eosinophils, total IgE, sputum exam

Spirometry is generally valuable in children $\geq$5 years of age; however some children cannot conduct the maneuver depending on developmental ability. Spirometry measurements (forced expiratory volume in 1 second [FEV_1], forced vital capacity [FVC], and the ratio of forced expiratory volume in 1

second to forced vital capacity [FEV_1/FVC]) before or after the patient inhales a short-acting bronchodilator should be undertaken for patients in whom the diagnosis of asthma is being considered. Airflow obstruction is indicated by reduced FEV_1 and FEV_1/FVC values relative to reference or predicted values. Significant reversibility is indicated by an increase of $\geq$12 percent and 200 mL in FEV_1 after inhaling a short-acting bronchodilator. (See the Discussion and References section of the original guideline document for information concerning differential diagnosis possibilities for asthma.)

4. Acute Asthma?

Symptoms of an acute asthma episode include progressive breathlessness, cough, wheezing, or chest tightness. An acute asthma episode is characterized by a decrease in expiratory airflow that can be documented and quantified by measurement of lung function (spirometry or PEFR). (Note that the algorithm is intended for treatment of outpatients. Critically ill patients are beyond the scope of this guideline.)

Indications for emergency care include:

- Peak flow less than 50% predicted normal
- Failure to respond to a beta agonist
- Severe wheezing or coughing
- Extreme anxiety due to breathlessness
- Gasping for air, sweaty, or cyanotic
- Rapid deterioration over a few hours
- Severe retractions and nasal flaring
- Hunched forward

5. Management of Acute Asthma

Patients presenting with acute exacerbation of their asthma should receive prompt evaluation and treatment to improve symptoms in the short term, prevent recurrence of symptoms, and provide for follow-up. The following is an outline of management:

Review history and physical exam, which may include:

- History
    - Severity of symptoms, limitations, and sleep disturbance
    - Duration of symptoms
    - Current medical treatment plan
    - Adherence to medical treatment plan
    - Rescue medication use:
        - recent use of short acting $beta_2$-agonists
        - number of bursts of oral steroids in past year
    - Review Asthma Action Plan and daily charting of peak flows
    - Previous emergency room (ER) visits or hospitalization
    - Record triggers:
        - Upper respiratory infection (URI)
        - Bronchitis, pneumonia
        - Exposure to allergens or irritants
        - Exercise

- Physical exam
    - Vital signs
    - Auscultation of chest
    - Peak flow rate or FEV_1
    - Use of accessory muscles
    - Alertness
    - Color
- Laboratory studies

  Treatment with bronchodilators should not be delayed for laboratory studies. Tests which may be useful include:

    - Oxygen (O_2) saturation (pulse oximetry)
    - Arterial blood gases (ABGs)
    - Chest x-ray (CXR)
    - Complete blood count (CBC)
    - Electrocardiogram (EKG)
    - Electrolytes
    - Theophylline concentration
- Assess severity: Assessment is based on history and physical exam

Treatment

Usual initial treatment is with short-acting nebulized $beta_2$-agonist (albuterol) 2.5 to 5 mg every 20 min up to 3 doses.

Alternatives:

Epinephrine: (1:1000)

- Adults: 0.3 to 0.5 mg subcutaneously or intramuscularly every 20 min up to 3 doses
- Pediatrics: 0.1 mg/kg up to 0.3 to 0.5 subcutaneously every 20 min up to 3 doses

Ipratropium added to nebulized $beta_2$-agonist (albuterol)

- Nebulized dose for adults and those over 12 years of age is 0.5 mg every 4 hours. Not Food and Drug Administration (FDA)-approved for any indication in those under 12 years of age.
- Ipratropium is not currently FDA-approved for use in asthma.

Levalbuterol

- Dose for adolescents over 12 years of age and adults is 0.63 mg (via nebulizer) three times per day (TID) (every 6-8 hours); may increase to 1.25 mg via nebulizer three times per day (every 6-8 hours) if patient does not exhibit adequate response.
- Dose for children 6 to 11 years of age is 0.31 mg (via nebulizer) TID. Routine dosing should not exceed 0.63 mg TID.
- Not FDA-approved for those under 12 years of age.

Assess Response

Good Response

Peak flow or FEV_1 >70% predicted normal
No wheezing on auscultation

Incomplete Response

Peak flow or FEV_1 50 to 70% predicted normal
Mild wheezing
Consider hospitalization, particularly for high-risk patients

- Past history of sudden severe exacerbation
- Prior intubation for asthma
- Two or more hospitalizations for asthma in the past year
- Three or more emergency care visits for asthma within the past year
- Hospitalization or an emergency care visit for asthma within the past month
- Use of >2 canisters per month of inhaled short-acting $beta_2$-agonists
- Current use of systemic corticosteroids or recent withdrawal from systemic corticosteroids
- Difficulty perceiving airflow obstruction or its severity
- Comorbidity, as from cardiovascular disease or chronic obstructive pulmonary disease
- Serious psychiatric disease or psychosocial problems
- Low socioeconomic status and urban residence
- Illicit drug use
- Sensitivity to Alternaria

Poor Response

Peak flow or FEV_1 <50% predicted normal
No improvement in respiratory distress
Strongly consider hospitalization
Continue inhaled $beta_2$-agonist every 60 minutes
Start oral prednisone unless contraindicated

- Adult: short course "burst" 40 to 60 mg/day as single or 2 divided doses for 3 to 10 days
- Pediatric: short course "burst" 1 to 2 mg/kg day, maximum 60 mg/day for 3 to 10 days

Home Treatment and Revised Asthma Action Plan

Medications

- Inhaled $beta_2$-agonist every 2 to 6 hours
- Initiate or increase anti-inflammatory medication:
    - inhaled corticosteroids
    - cromolyn/nedocromil

    - consider leukotriene modifiers
- Strongly consider systemic corticosteroids in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse.
- Antibiotics are not routinely used but may be warranted if patient has signs of acute bacterial infection, fever, and purulent sputum.

Education

- Teach or check inhaler technique/teach nebulizer use.
- Explain medications.
- Review action plan.
- Monitor peak flow.
- Reinforce trigger control.

Follow-up

- All patients need return appointment for management of asthma.
- Review and discuss signs or symptoms requiring emergent care.

Evidence supporting this conclusion is of classes: A, D, R

6. Interval Evaluation

Interval evaluation should include the following:

Medical History

- Disruption of usual activities (work, school, home)
- Sleep disturbance
- Level of usage of short-acting $beta_2$-agonist
- Adherence to medical treatment plan
- Interval exacerbation of symptoms (either treated by self or a health care provider)
- Symptoms suggesting comorbid conditions or alternative diagnosis
- Side effects of medications

Evidence supporting this conclusion is of classes: C, D

Assess Asthma Triggers/Allergens

- Inquire about exposure to triggers and allergens (e.g., occupational, pets, smoke).
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens.

Physical Examination

- Assess signs associated with asthma, concurrent illness or medication side effects.
- Height in children

- Head, eyes, ears, nose, throat, lungs, heart, skin

Measure Pulmonary Function

It is important to measure pulmonary function at each follow-up visit. The two main methods are spirometry and peak expiratory flow rate (PEFR).

Spirometry Recommended

- For initial diagnosis or to reassess or confirm diagnosis
- After treatment is initiated or changed, and once symptoms and PEFR have stabilized to document attainment of "near normal pulmonary function"
- At least every 1 to 2 years to assess maintenance of airway function; more often as severity indicates

PEFR:
Used for follow-up, not for diagnosis

During interval assessment the clinician should question the patient and review records to evaluate the frequency, severity, and causes of exacerbation. Triggers that may contribute should be reviewed. All patients on chronic maintenance medication should be questioned about exposure to inhalant allergens.

Evidence supporting this conclusion is of class: C

Consider Specialty Consultation

- Adults with severe persistent asthma, consider for moderate persistent asthma
- Children with moderate to severe persistent asthma, consider for mild persistent asthma
- Poorly controlled or complex asthma including previous life-threatening asthma exacerbation, or asthma exacerbations requiring more than 2 bursts of oral corticosteroids in 1 year, or asthma complicated by other medical or psychosocial conditions
- Additional diagnostic evaluations and/or testing (e.g., allergy skin testing, bronchoprovocation)
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens
- Evaluation and treatment of allergy (e.g., address occupation-related asthma, environmental counseling, immunotherapy)
- Patients who require additional or intensive asthma education not otherwise available

7. Assess Asthma Severity

Step 1: Mild Intermittent

- Symptoms $\leq$2 times a week

- Asymptomatic and normal peak expiratory flow (PEF) between exacerbations
- Exacerbations are brief (few hours to a few days)
- Nighttime symptoms $\leq$2 times a month
- FEV_1 or PEF $\geq$80 percent predicted and PEF variability $\leq$20 percent

Step 2: Mild Persistent

- Symptoms $\geq$2 times a week but $\leq$1 time a day
- Exacerbations may affect activity
- Nighttime symptoms $\geq$2 times a month
- FEV_1 or PEF $\geq$80 percent predicted and PEF variability 20 to 30 percent

Step 3: Moderate Persistent

- Daily symptoms
- Daily use of inhaled short-acting $beta_2$-agonists
- Exacerbations affect activity
- Exacerbations $\geq$2 times a week; may last days
- Nighttime symptoms $\leq$1 time a week
- FEV_1 or PEF $\geq$60 percent and $\leq$80 percent predicted
- PEF variability $\geq$30 percent

Step 4: Severe Persistent

- Continual symptoms
- Limited physical activity
- Frequent exacerbations
- Frequent nighttime symptoms
- FEV_1 or PEF $\leq$60 percent and PEF variability $\geq$30 percent

Evidence supporting this conclusion is of classes: M, R

8. Step Care of Pharmacologic Treatment

The aim of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimize the risk for adverse effects. The stepwise approach to therapy in which the dose and number of medications and frequency of administration are increased as necessary and decreased when possible is used to achieve this control. Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations.

Inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and leukotriene receptor antagonists are an alternative--although not preferred--treatment.

[Conclusion Grade I: See Discussion Appendix A, Conclusion Grading Worksheet -- Annotation #8 (Leukotriene Receptor Antagonists [LTRAs]) in the original guideline document.]

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
Step 1 - Mild Intermittent • Symptoms ≤2 times a week • Asymptomatic and normal PEF between exacerbations • Exacerbations are brief (few hours to a few days) • Nighttime symptoms ≤2 times a month • FEV_1 or PEF ≥80% predicted and PEF variability ≤20%	No daily medications needed
Step 2 - Mild Persistent • Symptoms ≥2 times a week but ≤1 time a day • Exacerbations may affect activity • Nighttime symptoms ≥2 times a month • FEV_1 or PEF ≥80 percent predicted and PEF variability 20-30%	Daily medication: • Inhaled corticosteroids (low dose)(preferred) OR • Leukotriene modifiers, theophylline, nedocromil, or cromolyn
Step 3 - Moderate Persistent • Daily symptoms • Daily use of inhaled short-acting $beta_2$-agonists • Exacerbation affects activity • Exacerbations >2 per week, may last days • Nighttime symptoms >1 time a week • FEV_1 or PEF ≥60% - ≤80% predicted	Daily medications: • Inhaled corticosteroid (medium dose or high dose) plus inhaled long-acting $beta_2$-agonist (preferred) OR • Inhaled corticosteroid (medium dose) plus leukotriene modifier,

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
• PEF variability $\geq$30%	theophylline, or oral long-acting beta$_2$-agonist
Step 4 - Severe Persistent • Continual symptoms • Limited physical activity • Frequent exacerbations • Frequent nighttime symptoms • FEV_1 or PEF $\leq$60% and PEF variability $\geq$30%	Daily medications: • Inhaled corticosteroid (medium dose or high dose) • PLUS: Long-acting beta$_2$-agonist (preferred) and/OR Leukotriene modifier and/OR Theophylline Recommended for uncontrolled asthma: Oral corticosteroids (see Table 8D in original guideline document)
Step down: Review treatment every 1-6 months; a gradual stepwise reduction in treatment may be possible.	Step up: If control not maintained, consider step up. First review patient medication technique, adherence, and environmental control (avoidance of allergens or other factors that contribute to asthma severity)
Quick relief: • Short-acting bronchodilator: inhaled beta$_2$-agonists as needed for symptoms • Intensity of treatment will depend on severity of exacerbation. • Use of short-acting inhaled beta$_2$-agonists on a daily basis, or increasing use, indicates the need for additional long-term control therapy.	

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
Education: Step 1: • Teach basic facts about asthma. • Teach inhaler/spacer/holding chamber technique. • Discuss role of medications. • Develop self-management plan. • Develop action plan for when and how to take rescue actions, especially for patient with a history of severe exacerbations. • Discuss appropriate environmental control measures to avoid exposure to known allergens and irritants. Step 2: • Teach self-monitoring. • Refer to group education if available. • Review and update self-management plan. Step 3: Refer to individual education/counseling.	

Refer to Tables 8B through 8D in the original guideline document for a detailed discussion of usual dosages for long-term medications, estimated comparative daily dosage for inhaled corticosteroids, and usual dosages for quick-relief medications.

9. Asthma Education

Patient education is essential for successful management of asthma. It should begin at the time of diagnosis and be ongoing. Patient education includes basic facts about asthma, inhaler technique, written action plan including home peak flow monitoring, environmental control measures, and emphasizing need for regular follow-up visits.

Refer to the original guideline document for detailed recommendations on asthma education.

A sample Asthma Action Plan is attached in Annotation Appendix A of the original guideline document.

Supervised self-management, using patient education and adjustments of anti-inflammatory medication based on PEF or symptoms coupled with regular medical review, reduces asthma morbidity. This reduction includes lost work days, unscheduled office visits, and emergency room (ER) and hospital admissions. [Conclusion Grade I: See Discussion Appendix B of the original guideline document, Conclusion Grading Worksheet – Annotation #9]

Evidence supporting this conclusion is of classes: A, D, R

10. Schedule Regular Follow-up Visits

Regularly scheduled follow-up visits are essential to ensure that control is maintained and the appropriate step down in therapy is considered. The exact frequency of clinician visits is a matter of clinical judgment.

Severity	Regular Follow-up Visit
Mild intermittent	6-12 months
Mild persistent	6 months
Moderate persistent	3 months
Severe persistent	1 to 2 months and as often as needed to establish control

Definitions:

Rating Scheme for the Strength of the Evidence

Classes of Research Reports

A. Primary Reports of New Data Collection

Class A

- Randomized, controlled trial

Class B

- Cohort study

Class C

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test

- Population-based descriptive study

Class D

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R

- Narrative review article
- Consensus statement
- Consensus report

Class X

- Medical opinion

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence that directly supports or refutes the conclusion.

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Diagnosis and Management of Asthma.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Accurate diagnosis and assessment of asthma severity
- Effective long-term control of persistent asthma through the use of anti-inflammatory medication
- Effective partnership of patients and parents with health care professionals through education and use of written action plans

POTENTIAL HARMS

Risk of Adverse Effects Associated with Asthma Pharmacotherapy

- Common side effects from inhaled steroids include oral candidiasis and dysphonia.
- Inhaled glucocorticoids used to treat asthma have been shown to have deleterious effects on bone mineral density and markers of bone mineral metabolism. The risk of fracture attributable to inhaled or nasal glucocorticoids is uncertain.
- Beta$_2$-agonists may cause tachycardia, tremor, or nervousness.
- Individuals on long-term oral corticosteroids or frequent bursts of steroids need to be monitored for complications of corticosteroid use such as osteoporosis, hypertension, diabetes, and Cushing's disease.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the valuation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

The following detailed measurement strategies are presented to help close the gap between clinical practice and the guideline recommendations.

Priority Aims and Suggested Measures for Health Care Systems

1. Promote the accurate assessment of asthma severity through the use of objective measures of lung function.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with asthma with spirometry or peak flow documented at the last visit.
   b. Percentage of patients with asthma, for whom a peak flow meter is appropriate, who report using a home peak flow meter.
   c. Percentage of patients with asthma with any assessment of asthma severity documented at the last visit.

2. Promote long-term control of persistent asthma through the use of anti-inflammatory drug therapy.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with persistent asthma who are on anti-inflammatory medication.
3. Promote the partnership of patients and/or their parents with health care professionals through education and use of written action plans.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with asthma with an asthma action plan in the medical record.
   b. Percentage of patients with asthma with education about asthma documented in the medical record.

Possible Success Measure #1a

Percentage of patients with asthma with spirometry or peak flow meter reading documented in the medical record at the last visit.

Population Definition

Patients age 5 through 55 years diagnosed with asthma, continuously enrolled for 6 months.

Data of Interest

# of patients with asthma with spirometry or peak flow meter reading documented at the last visit
total # of patients ages 5-55 with asthma

Numerator/Denominator Definitions

Numerator:
Documented is defined as any evidence in the medical record that spirometry or peak flow reading was done at the last visit as recommended in the guideline.

Denominator:
Patients with a specific diagnosis code (see the original guideline document for specific ICD-9 codes), continuously enrolled for 6 months.

Method/Source of Data Collection

Data may be collected electronically using the claims/encounter database or the enrollment database. Medical groups should identify patients with asthma seen at the clinic. Each medical group can then generate a list of all eligible patients with asthma seen during the target month/quarter. A random sample of 20 charts can be chosen from this list. The eligible patients are those who are 5 to 55 years old and have been diagnosed with asthma. The patient medical records are reviewed

for any evidence that spirometry or peak flow meter reading was done at the last visit as recommended in the guideline.

Time Frame Pertaining to Data Collection

A minimum of 20 charts per month can be reviewed.

Notes

It is important to periodically assess pulmonary function. The main methods are spirometry or peak expiratory flow rate (PEFR). Spirometry is more precise and yields more information than peak expiratory flow rate. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of peak expiratory flow rate (i.e., very young or elderly, neuromuscular or orthopedic problems). Peak expiratory flow rate provides a simple, quantitative, and reproductive measure of severity of airflow obstruction. The results are more reliable if the same type and preferably the patient's own meter are used.

Possible Success Measure #2a (Children)

Percentage of children with persistent asthma who are on anti-inflammatory medication.

Population Definition

Children aged 17 and under with persistent asthma, continuously enrolled for 6 months.

Data of Interest

children in denominator who have one or more prescriptions for inhaled corticosteroids medications
of children with persistent asthma

Numerator/Denominator Definitions

Numerator:
Among the children in the denominator, the number who have one or more prescriptions for anti-inflammatory medications:

- Beclomethasone HFA (Vanceril, Beclovent, QVAR)
- Cromolyn sodium (Intal)
- Triamcinolone (Azmacort)
- Fluticasone (Flovent, Advair)
- Budesonide (Pulmicort)
- Flunisolide (Aerobid)

Denominator:
Children with persistent asthma (see the original guideline document for specific ICD-9 codes), continuously enrolled for 6 months.

Method/Source Of Data Collection

This measure may be collected electronically using the pharmacy database, the claims/encounter database, and the enrollment database.

Time Frame Of Data Collection

It is suggested that data are collected quarterly.

Notes

Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations.

Possible Success Measure #2a (Adults)

Percentage of adults with persistent asthma who are on anti-inflammatory medication.

Population Definition

Adults age 18 through 39 with persistent asthma, continuously enrolled for 6 months.

Data of Interest

# of adults in the denominator who have 1 or more prescriptions for inhaled corticosteroids medications
# of adults with persistent asthma

Numerator/Denominator Definition

Numerator:
Persons in the denominator who have 1 or more prescriptions filled for inhaled anti-inflammatory medications.

Inhaled anti-inflammatory medications are:

- Beclomethasone HFA
- Triamcinolone
- Fluticasone
- Flunisolide
- Budesonide
- Fluticasone propionatel salmeterol DPI

Denominator:
Adults age 18 through 39 with persistent asthma (see the original guideline document for specific ICD-9 codes), continuously enrolled for 6 months, identified

by having received one or more refills of the following medications during the 6 month period:

- Beclomethasone HFA
- Flunisolide
- Budesonide
- Triamcinolone
- Fluticasone
- Fluticasone propionatel salmeterol DPI

Method/Source of Data Collection

Data may be collected electronically using the pharmacy database, the claims/encounter database or the enrollment database.

Time Frame Pertaining To Data Collection

It is suggested that data are collected quarterly.

Possible Success Measure #3b

Percentage of patients with asthma with education about asthma documented in the medical record.

Population Definition

Patients age 5 through 55 years diagnosed with asthma continuously enrolled for 6 months.

Data of Interest

# of patients in the denominator with documentation in the record of patient education about asthma
total # of patients with asthma whose medical records are reviewed

Numerator/Denominator Definitions

Numerator:
Documented is defined as any evidence in the medical record that a clinician provided patient (or parent) education related to:

- Basic facts about asthma
- Role of medications
- Skills (in managing asthma)
- Environmental control measures
- When and how to take actions
- Need for follow-up visits

Denominator:
Patients with a specific diagnosis code of (see the original guideline document for specific ICD-9 codes), continuously enrolled for 6 months.

Method/Source of Data Collection

Data may be collected electronically using the claims/encounter database or the enrollment database. Medical groups should identify patients with asthma seen at the clinic. Each medical group can then generate a list of all eligible patients with asthma seen during the target month/quarter. The eligible patients are those who are 5 to 55 years old and have been diagnosed with asthma. A random sample of 20 charts can be chosen from this list. The patients´ medical records will be reviewed for any evidence that a clinician provided patient education.

Time Frame Pertaining to Data Collection

A minimum of 20 charts per month can be reviewed.

Notes

Patient education is essential for successful management of asthma. It should begin at the time of diagnosis and be ongoing.

Systems Approaches to Implementation for This Guideline

1. Facilitate timely and accurate diagnosis of asthma and asthma severity.
2. Educate providers in the use of spirometry as a diagnostic tool.
3. Educate providers and patients in the importance of developing and maintaining an asthma action plan and assessing adherence.

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 May. 49 p. [37 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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1998 Jun (revised 2003 May)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, RiverWay Clinics, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians

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GUIDELINE COMMITTEE

Respiratory Steering Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. It is not assumed that these financial interests will have an adverse impact on guideline content. They simply are noted here to fully inform users of the guideline.

All work group members: none declared.

GUIDELINE STATUS

This is the current release of guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2002 May. 43 p.

The next revision of the guideline is scheduled for March 2003.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Diagnosis and management of asthma. In: ICSI pocket guidelines. April 2003 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2003 Mar p. 214-9.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

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